IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE:	)
AREDIA and ZOMETA PRODUCTS	)
LIABILITY LITIGATION	) NO. 3-06-MD-1760
	) JUDGE CAMPBELL
This Document Relates To Case Number:	)
3:08-0925 (Talley)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 3452). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part.

FACTS

Plaintiff has alleged that Defendant's drugs, Aredia and Zometa, caused her to develop osteonecrosis of the jaw ("ONJ"). She asserts claims for strict liability and negligence, including negligence *per se*. Defendant has moved for summary judgment on all Plaintiff's claims.

SUMMARY JUDGMENT

Summary judgment is appropriate where there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Pennington v. State Farm Mut. Automobile Ins. Co.*, 553 F.3d 447, 450 (6th Cir. 2009). The party bringing the summary judgment motion has the initial burden of informing the Court of the basis for its motion and identifying portions of the record that demonstrate the absence of a genuine dispute over material facts. *Rodgers v. Banks*, 344 F.3d 587, 595 (6th Cir. 2003). The moving party may satisfy this burden by presenting affirmative evidence that negates an element of the non-moving party's claim or by demonstrating an absence of evidence to support the nonmoving party's case. *Id*.

In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Pennington*, 553 F.3d at 450; *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). The mere existence of a scintilla of evidence in support of the nonmoving party's position will be insufficient to survive summary judgment; rather, there must be evidence on which the jury could reasonably find for the nonmoving party. *Rodgers*, 344 F.3d at 595 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)).

STRICT LIABILITY

Plaintiff has conceded that her claims for strict liability, design defect and manufacturing defect fail as a matter of North Carolina law. Docket No. 3570, pp. 20-21. Accordingly, Defendant's Motion for Summary Judgment is GRANTED on Plaintiff's strict liability, design defect and manufacturing defect claims, and those claims are DISMISSED.

CAUSATION

Defendant argues that Plaintiff cannot establish that Aredia and/or Zometa caused her ONJ. The Court has previously found that there are genuine issues of material fact as to whether Aredia and Zometa generally can cause ONJ, and that holding applies here as well. Defendant contends that Plaintiff has no admissible expert testimony[1] to show that these drugs caused Plaintiff's ONJ specifically.

Under North Carolina law, which the parties agree applies in this case, a manufacturer may not be held liable for a claim based on inadequate warnings unless the failure to provide adequate

[1] Where an injury is complicated, such as in this case, expert medical testimony on the issue of causation must be provided. *Driggers v. Sofamore*, 44 F.Supp.2d 760, 764-65 (M.D. N.C. 1998).

warnings was a proximate cause of the Plaintiffs' injuries. *DeWitt v. Eveready Battery Co.*, 550 S.E.2d 511, 517-18 (N.C. Ct. App. 2001); *see also* N.C. Stat. § 99B-5(a). In addition, to hold a defendant responsible for a plaintiff's injuries in a negligence[2] action, defendant's negligence must have been a substantial factor of the particular injuries for which the plaintiff seeks recovery. *Gaines v. Cumberland County Hospital System, Inc.*, 672 S.E.2d 713, 716 (N.C. Ct. App. 2009).

Here, as in the *Brown* case, Plaintiff has offered expert testimony from Dr. Yoh Sawatari, who opines that Ms. Talley, after receiving more than seven years of Aredia and Zometa, suffered from bisphosphonate-induced osteonecrosis of the jaw, "based on the significant administration of IV bisphosphonates and the development of necrotic bone which was refactory to treatment." Docket No. 3570-1. The Court has, contemporaneously herewith, denied Defendant's Motion to Exclude the testimony of Dr. Sawatari. Therefore, Plaintiff has presented sufficient evidence to establish a factual dispute on this issue, and Defendant's Motion for Summary Judgment on the issue of specific causation is denied.

FAILURE TO WARN

Defendant next asserts that Plaintiff cannot establish that Defendant did not adequately warn about the alleged risk of harm. This Court has previously held that there are genuine issues of material fact as to the adequacy of Defendant's warnings, and that holding applies here as well. Defendant contends, however, that Plaintiff cannot show that any alleged failure to warn proximately caused her ONJ.

[2] Because North Carolina does not recognize strict liability in products liability actions, Plaintiffs' claims are based upon negligence. *See Driggers*, 44 F.Supp.2d at 766.

Defendant points to the fact that Plaintiff is still taking Zometa as evidence that additional warnings would have made no difference. It is undisputed that Plaintiff received Aredia or Zometa from 1999 to 2006. Plaintiff's oncologist, Dr. Levine, testified that he learned of the association between bisphosphonates and ONJ in October of 2004. At that point, he changed Plaintiff's dosage of Zometa from every month to every three months. Docket No. 3570-3, pp. 16-17 (Levine deposition, pp. 56-60). Plaintiff had already been on the bisphosphonate drugs for five years.

Plaintiff has stated under oath that, had she known of the risk of ONJ associated with Aredia and Zometa, she would have reduced her dosage earlier and would have insisted on greater vigilance and dental monitoring to protect her jaw. Docket No. 3570-5. The Court finds that Plaintiff has presented evidence sufficient to create a genuine issue of material fact as to whether different warnings would have change the behavior of Plaintiff's healthcare providers and/or Plaintiff in this case. Accordingly, Defendant's Motion for Summary Judgment on the issue of failure to warn is denied.

NEGLIGENCE *PER SE*

As with Mr. Brown, Plaintiff herein has admitted that the negligence *per se* doctrine does not create new causes of action. Docket No. 3570, p. 19. In addition, the Federal Food, Drug and Cosmetic Act ("FDCA") does not provide a private right of action under which plaintiffs may bring suit. The statute itself provides that all such proceedings for the enforcement or to restrain violations of the Act shall be by and in the name of the United States (with one exception not applicable here). 21 U.S.C. § 337(a). The Supreme Court has stated that the FDCA leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance with the Act. *Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S.Ct. 1012, 1018 (2001).

Therefore, to the extent that Plaintiff's negligence *per se* claim purports to be a separate cause of action, Defendant's Motion for Summary Judgment is granted. To the extent Plaintiff wishes to argue that the negligence *per se* doctrine creates some sort of standard by which to judge Defendant's behavior, the Court need not reach that issue and Defendant's Motion is moot.

CONCLUSION

For all these reasons, Defendant's Motion for Summary Judgment (Docket No. 3452) is GRANTED in part and DENIED in part. Plaintiff's claims for strict liability, design defect, manufacturing defect and negligence *per se* are DISMISSED.

IT IS SO ORDERED.

Todd Campbell

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE